BAXANO SURGICAL

APR 0 7 2014

510(k) Summary
Baxano Surgical MIS Pedicle Screw System

Submitter: Baxano Surgical, Inc.
110 Horizon Drive, Ste 230
Raleigh, NC 27615

Contact Person: Kristen Allen
Regulatory Project Manager
910-332-1733 (P)
910-332-1701 (F)
kristen.allen@baxsurg.com (e-mail)

Date Prepared: February 4, 2014

Trade Name: Baxano Surgical MIS Pedicle Screw System

Common Name: Spinal Pedicle Fixation Device

Device Product Code and Classification:

MNH, 888.3070, Class II, Spondylolisthesis Spinal Fixation Device System

MNI, 888.3070, Class II, Pedicle Screw Spinal System

NKB, 888.3070, Class III, Pedicle Screw Spinal System, For Degenerative Disc Disease

Predicate Device: **Life Spine® Conquest® Spinal System (K090320)**
CD Horizon® SOLERA™ Spinal System (K113174)

Device Description:
The Baxano Surgical MIS Pedicle Screw System is a multiple component system comprised of non-sterile, single-use implantable components fabricated from titanium alloy and cobalt chrome. When assembled, the components are implanted via a percutaneous, mini-open or open delivery to create a rigid structure to provide stabilization and promote spinal fusion. The system consists of an assortment of polyaxial cannulated pedicle screws, rods, cross connectors and locking caps, and associated instruments.

Indications and Intended use:
The Baxano Surgical MIS Pedicle Screw System is intended for posterior, non-cervical pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion for the following indications: (1) Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) Spondylolisthesis, (3) Trauma (i.e. fracture or dislocation), (4) Spinal stenosis, (5)

Curvatures (i.e. scoliosis, kyphosis, and/or lordosis), (6) Tumor, (7) Pseudoarthrosis and (8) Failed previous fusion.

Summary of Technological Characteristics:
The Baxano Surgical MIS Pedicle Screw System shares the same technological characteristics as the predicate device Life Spine® Conquest® Spinal System, including design, materials, cleaning/sterilization process, range of sizes, performance characteristics and indication for use. The Baxano Surgical MIS Pedicle Screw System implant components are supplied non-sterile and are single-use. The Cannulated, self-tapping pedicle screw implants are fabricated from Titanium alloy (Ti6Al4V ELI, ASTM F136) and Cobalt-chromium-molybdenum alloy (ASTM F1537). The subject device system also contains implantable rods (straight and lordosed), locking caps and cross connectors, which are fabricated from Titanium alloy (Ti6Al4V ELI, ASTM F136). The device provides correction and rigid stabilization of the spine during development of solid bone fusion following corrective spine surgery for a number of indications (listed above). The Baxano Surgical MIS Pedicle Screw System is designed to be implanted via a percutaneous, mini-open or open delivery method.

Summary of Performance Testing:
Non-clinical mechanical testing for the Baxano Surgical MIS Pedicle Screw System was performed on the worst case subject device in accordance with ASTM standards. Comparative testing was also performed including components of the Baxano Surgical MIS Pedicle Screw System and the predicate Conquest Pedicle Screw System.

Test	Standard
Static Compression	ASTM F1717-13
Static Torsion	ASTM F1717-13
Dynamic Compression	ASTM F1717-13
Axial Pullout	ASTM F543-07
Torque to Failure	ASTM F543-07
Axial Grip	ASTM F1798-97
Torsional Grip	ASTM F1798-97
Flexural Grip	ASTM F1798-97

For all test methods, the subject devices met or exceeded the requirements as established by the test protocol and applicable ASTM standards. The results demonstrated that the Subject device is substantially equivalent to the Predicate.

Substantial Equivalence:
Based on the comparison and performance testing analysis provided in this premarket notification submission, the Baxano Surgical MIS Pedicle Screw System has been shown to be substantially equivalent to the Life Spine® Conquest® Spinal System Pedicle Screw System (K090320) in indications for use, design, materials used, and device functional scientific technology as the cleared predicate Conquest System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 7, 2014

Baxano Surgical, Incorporated
Ms. Kristen Allen
Regulatory Project Manager
301 Government Center Drive, Suite 100
Wilmington, North Carolina 28403

Re: K133743
Trade/Device Name: Baxano Surgical MIS Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: February 4, 2014
Received: February 5, 2014

Dear Ms. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133743

Device Name
Baxano Surgical MIS Pedicle Screw System

Indications for Use *(Describe)*
The Baxano Surgical MIS Pedicle Screw System is intended for posterior, non-cervical pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion for the following indications: (1) Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) Spondylolisthesis, (3) Trauma (i.e. fracture or dislocation), (4) Spinal stenosis, (5) Curvatures (i.e. scoliosis, kyphosis, and/or lordosis), (6) Tumor, (7) Pseudoarthrosis and (8) Failed previous fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

James P. Bertram -S
2014.04.07 10:52:40 -04'00'

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